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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/647,991   | 08/26/2003  | John Moenning        | 7432-0046           | 2487             |
| 7590   | 01/25/2006  |                      | EXAMINER            |                  |
| INDIANO VAUGHAN ROBERTS & FILOMENA, P.A.<br>Suite 850<br>One North Pennsylvania Street<br>Indianapolis, IN 46204 |             |                      | ALI, SHUMAYA B      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3743                |                  |

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                            |                  |
|------------------------------|----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.            | Applicant(s)     |
|                              | 10/647,991                 | MOENNING ET AL.  |
|                              | Examiner<br>Shumaya B. Ali | Art Unit<br>3743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 November 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,5,6,9-12,24-27,30 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) 13-18,20,22,23,28,29 and 32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,5,6,9-12,24-27,30 and 34-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: detailed action.

## **DETAILED ACTION**

### ***Response to Amendment***

In response to the office action mailed on 6/2/2005, the applicant has amended claims 1,14,15,17,19,21,24,30,32, and 33; cancelled claims 3,4,7,8, and 31; added new claims 34-39; claims 13-18,20,22-23,28-29,32 remains withdrawn. Currently claims 1-2,5-6,9-12,24-27,30, 34-39 are pending.

### ***Response to Arguments***

1. The Applicant's remark filed on 11/3/05 is fully considered, however what the Applicant consider as the patentable subject matter: (1) the patient end portion comprising a flexible cannula having a source end disposed in the outside airspace, a middle portion extending through the dome portion, and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient can be overcome by a newly cited reference to McAuley et al. US Patent Application Publication 2003/0094178 A1; and (2) the exhaust port including an elbow, elbow of the exhaust line being positioned by the elbow to extend over the forehead of the patient can be overcome by a newly cited reference to Barnett et al. US Patent No. 6,412,488 B1.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter. Recitation “for use of a patient having a forehead, a mouth, and a nose having a naris” as seen in claims 1,21,24,30, and 38 are considered non-statutory subject matter.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1,21,30 34-37, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Recitations, “flexible cannula”, and “a middle portion” not found in the specification; as to claim 34 “a second flexible cannula”, claim 35 “first and second cannula”, “flexible”; claim 36 “first cannula to resist movement of the first cannula. Moved by the user”; claim 37, “a middle portion”, “second inspiratory port being sized for slidably receiving the second cannula...of the second cannula when not being moved by the user.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 1,21,30, 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which**

applicant regards as the invention. “Middle portion” as recited in the claims are not disclosed in the original disclosure, therefore, it is not clear which part of the tube is considered “middle portion”.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 5, 10,11,12, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Blasdell et al. US Patent 5,419,317 in view of McAuley et al. US Patent Application Publication 2003/0094178 A1.**

7. **As to claims 1,5,10,11, 12, and 21 Blasdell et al disclose** an anesthesia delivery device for use on a patient having a mouth and a nose having a naris, the delivery device being capable of being coupled to a ventilation system (**fig.21 reference object 142**) comprising all claimed limitation as cited in the previous office action mailed on 6/2/05 except for the patient end portion comprising a flexible cannula having a source end disposed in the outside airspace, a middle portion extending through the dome portion, and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient. However, at the time the invention was made such limitation was known to one of ordinary skills in the art. McAuley et al. teaches a nasal positive pressure device in figures 11-13 where a nasal

snap flap (“mask”) provided a cup like device (“dome portion”) that is fitted around the patient’s nose (see 0058), further teaches inspiratory gas being provided within each nostril (see 0061) of a patient through nasal cannula that goes though the nasal nap flap. Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to modify the cannula of Blasdell et al. in view of McAuley et al. in order to provide a cannula that extends though the dome portion for the purposes of engaging and securing the cannula within the nares (see 0058) to ensure treatment air/inspiratory gas being delivered to the patient, thereby resulting in increased treatment compliance (see 0008)

**Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blasdell et al. US Patent 5,419,317, McAuley et al. US Patent Application Publication 2003/0094178 A1, and in view of Schauweker US Patent 2,462,005**

**13. As to claim 2, Blasdell et al do not disclose the anesthesia delivery device of claim 1 further comprising an eye shield having a shield attachment mechanism for attaching the eye shield to the facemask such that the eye shield covers the eyes of the patient. As to claim 2, Schauweker teaches a face shield of a flat substantially rectangular shaped transparent member (see col.4 lines 37-39) with a pair of downwardly extending convergent straps, which attach the eye shield to a respirator (see col.2 lines 40-46). Therefore, it would have been obvious to one of ordinary skill in the art to add a flat eye shield with attachment mechanism to the invention of Blasdell in view of Schauweker for the purposes of preventing possible injuries to the eyes and face from dust (see col.2 lines 28-29) and biohazard substances.**

**Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blasdell et al. US Patent 5,419,317, McAuley et al. US Patent Application Publication 2003/0094178 A1, and in view of Kwok et al. US Patent 6,112,746**

**21. As to claim 19, Blasdell et al do not disclose the anesthesia delivery device of claim 1 wherein the vent is formed by an aperture in the facemask, As to claim 19, Kwok et al. teach a nasal mask with vent openings on the mask body by which expired gas is exhausted (see col.4 lines 9-10). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was to modify the mask of Blasdell in view of Kwok in order to provide vents on the mask body for the purposes of allowing expired gas to be exhausted from the interior air-space of the mask.**

**Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blasdell et al. US Patent 5,419,317, McAuley et al. US Patent Application Publication 2003/0094178 A1, Kwok et al. US Patent 6,112,746, and in view of Vanuch US Patent 5,243,78**

**23. As to claim 6, Blasdell et al do not disclose the anesthesia delivery device of claim 5 further comprising a cushion member attached to the lower edge of the dome portion of the facemask, wherein the cushion member contains a bladder filled with a gas, and is scented. As to claim 6, Kwok et al. teach a nasal mask cushion to sealingly connect a mask to a wearer's face (see col.1 lines 65-66). Also teach a seal is formed with a deformable membrane (see col.3 line 47-50, col.4 line 26). As to claim 6, Vanuch teach scented mask is intended primarily for quick and convenient use and availability in situations where the wearer seeks to avoid experiencing unpleasant odor (see col.1 lines 22-26). Therefore, it would have been obvious to one of**

**ordinary skills in the art at the time the invention was made to modify the nosepiece of Blasdell in view of Kwok et al. in order to provide the mask with a deformable cushioning member for the purposes of providing a tight seal along the mask's periphery and provide the mask of Fisher with scented material in view of Kwok et al. and in further view of Vanuch for the purposes of avoid unpleasant odor.**

**Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blasdell et al. US Patent 5,419,317, McAuley et al. US Patent Application Publication 2003/0094178 A1, and in view of Muto et al. US Patent 4,454,880**

**24. As to claim 9, Blasdell et al. disclose the anesthesia delivery device of claim 1 wherein the face mask further comprises an inspiratory port (fig.15 reference object 23), the inspiratory gas line passing from the outside air space exterior to the dome portion of the face mask, however do not disclose into the inside air space between the dome portion of the face mask and the patient's nose through the inspiratory port. As to claim 9, Muto et al. teach a soft flexible shell shaped to fit over and cover the nose of a patient (see col.4 lines 13-15), and gas supply tubes (see fig.3 reference objects 56,57) passing through the shell and in contact with nozzles (fig.2 reference object 62) to provide fluid to the patient so that the fluid does not directly jet into the nostrils to possibly burn and dry the nasal mucous, or to cause nasal and septal necrosis (see col.3 lines 35-40). Therefore, it would have been obvious to one of ordinary skills in the art to modify the invention of Blasdell in view of Muto in order to pass the gas supply tube into the mask and patient's nose for the purposes of reducing nasal tissue damage that can be**

**caused by the pressure of the fluid/gas and also preventing leakage by ensuring gas flow into the nostril.**

**Claims 24-27, 30,34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blasdell et al. US Patent 4,265,239, Schauweker US Patent 2,462,005, Kwok et al. US Patent 6,112,746, and in view of Barnett et al. US Patent No. 6,412,488 B1**

**16. Blasdell et al disclose an anesthesia delivery device for use on a patient having a mouth and a nose having a naris, the delivery device being capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to the patient and an exhaust gas output for delivering gas from a patient to the ventilation system comprising all claimed limitation as cited in the previous office action mailed on 6/2/05 except for a cushion member attached to the lower edge of the dome portion, as to claim 24, Kwok et al. teach a nasal mask cushion to sealingly connect a mask to a wearer's face (see col.1 lines 65-66). Also teach a seal is formed with a deformable membrane (see col.3 line 47-50, col.4 line 26). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the nosepiece of Blasdell in view of Kwok et al. in order to provide the mask with a deformable cushioning member for the purposes of providing a tight seal along the mask's periphery), and an eye shield having a shield attachment mechanism for attaching the eye shield to the face mask such that the eye shield covers the eyes of the patient (as to claim 24, Schauweker teaches a face shield of a flat substantially rectangular shaped transparent member (see col.4 lines 37-39) with a pair of downwardly extending convergent straps which attach the eye shield to a respirator (see col.2 lines 40-46). Therefore, it would have been obvious to one**

**of ordinary skill in the art to add a flat eye shield with attachment mechanism to the invention of Blasdell in view of Schauweker for the purposes of preventing possible injuries to the eyes and face from dust (see col.2 lines 28-29) and biohazard substances), exhaust port including an elbow, an exhaust line being positioned by the elbow to extend over the forehead of the patient. However, such limitations are known in the art, taught by Barnett et al. teach in figure 6, a nasal mask assembly with an exhaust tube in communication with the mast via elbow connection. As also depicted in the figure that the tube is situate above the forehead of a patient (see fig. 6). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the exhaust system of Blasdell in view of Barnett et al. as a matter of design choice since position of the exhaust tube either going toward the forehead or chin is well known in the art.**

**Claims 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blasdell et al. US Patent 4,265,239, Schauweker US Patent 2,462,005, Kwok et al. US Patent 6,112,746, Barnett et al. US Patent No. 6,412,488 B1 in view of McAuley et al. US Patent Application Publication 2003/0094178 A1.**

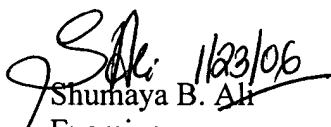
**Blasdell et al. do not teach** limitations cited in claim 39, however such limitations are taught by McAuley et al. **McAuley et al. teaches** a nasal positive pressure device in figures 11-13 where a nasal snap flap (“mask”) provided a cup like device (“dome portion”) that is fitted around the patient’s nose (see 0058), further teaches inspiratory gas being provided within each nostril (see 0061) of a patient through nasal cannula that goes though the nasal nap flap. **Therefore, it would have been obvious to one of ordinary skills in the art at the time of the**

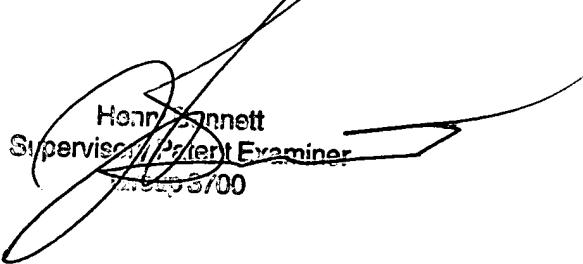
**invention to modify the cannula of Blasdell et al. in view of McAuley et al. in order to provide a cannula that extends though the dome portion for the purposes of engaging and securing the cannula within the nares (see 0058) to ensure treatment air/inspiratory gas being delivered to the patient, thereby resulting in increased treatment compliance (see 0008)**

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shumaya B. Ali  
Examiner  
Art Unit 3743

  
Henry Bennett  
Supervisory Patent Examiner  
Art Unit 3743

**U.S. Patent**

**5,419,317**

